K122752

BRANAN BMC MEDICAL CORP

JAN 30 2013

5.0 510(k) Summary

510(k) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

Establishment Name and Address

Branan Medical Corporation
140 Technology Dr., Bldg. 400
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Date Prepared: September 5, 2012

Proprietary and Trade Name

Fastect® II PPX Drug Screen Dipstick
Fastect® II Drug Screen Dipstick
QuickTox® Drug Screen Dipcard

Common Name

Immunochromatographic test for the qualitative detection of Propoxyphene in urine.

Classification Panel

Propoxyphene Test System

Product Code

JXN

Classification Number

21 CFR, 862.3700

Device Classification

The Propoxyphene test systems are classified as Class II devices with moderate complexity. The Fastect® II Drug Screen Dipstick with Propoxyphene and QuickTox® Drug Screen Dipcard with Propoxyphene are used to provide only a preliminary result. All preliminary positive test results obtained with these devices must be confirmed by another test method, preferably GC/MS or LC/MS confirmatory analysis.

Substantially Equivalent Devices

K041685 – ACON MULTI-CLIN Drug Screen Test Device

Device Description

The Fastect® II Drug Screen Dipstick with Propoxyphene and QuickTox® Drug Screen Dipcard with Propoxyphene contain multiple drugs and drug metabolites in addition to Propoxyphene. Propoxyphene is added as a new analyte. The Fastect® II PPX Drug Screen Dipstick only contains the propoxyphene analyte. All dipstick and dipcard devices are based on the principle of highly specific immunochemical reactions between antigens and antibodies and all devices utilize a competitive immunoassay procedure in which an immobilized drug conjugate competes with the drug present in urine for limited antibody binding sites.

The Fastect® II PPX Drug Screen Dipstick, Fastect® II Drug Screen Dipstick and QuickTox® Drug Screen Dipcard devices are standardized to detect Propoxyphene in human urine at a cutoff concentration of 300 ng/ml. These tests can be performed without the use of any additional instruments.

A control band with a different antigen/antibody reaction is added to the immunochromatographic membrane strip and should always appear regardless of the presence of drug or metabolite. The appearance of the control band during testing indicates that the test has completed and the test is valid.

Intended Use

The Fastect® II PPX Drug Screen Dipstick is lateral flow immunoassay *in vitro* diagnostic screen test for qualitative detection of propoxyphene at or above 300ng/ml in human urine.

The Fastect® II Drug Screen Dipstick and QuickTox® Drug Screen Dipcard are lateral flow immunoassay *in vitro* diagnostic screen tests for the qualitative detection of cocaine (at or above 300ng/ml), opiates (at or above 300ng/ml), methamphetamine (at or above 500ng/ml), THC (at or above 50ng/ml), amphetamine (at or above 1000ng/ml), phencyclidine (at or above 25ng/ml), benzodiazepines (at or above 300ng/ml), barbiturates (at or above 300ng/ml), methadone (at or above 300ng/ml), tricyclic antidepressants (at or above 1000ng/ml), MDMA (at or above 500ng/ml), oxycodone (at or above 100ng/ml), buprenorphine (at or above 10ng/ml), or propoxyphene (at or above 300ng/ml) in human urine. It is for prescription point-of-care use and not intended for over-the-counter sale to non-professionals.

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Indications for Use

The Fastect® II Drug Screen Dipstick Test is a lateral flow immunoassay for the rapid detection of propxyphene in human urine at or above 300 ng/mL.

The Fastect® II Drug Screen Dipstick and QuickTox® Drug Screen Dipcard are lateral flow immunoassay for the rapid detection of multiple drugs and drug metabolites in human urine at or above the following cutoff concentration:

THC	11-nor-Δ9-Tetrahydrocannabinol-9-carboxylic acid	50 ng/ml
COC	Benzoylecgonine	300 ng/ml
OPI	Morphine	300 ng/ml
MET	Methamphetamine	500 ng/ml
AMP	Amphetamine	1000 ng/ml
PCP	Phencyclidine	25 ng/ml
BZO	Oxazepam	300 ng/ml
BAR	Secobarbital	300 ng/ml
MTD	Methadone	300 ng/ml
TCA	Nortriptyline	1000 ng/ml
MDMA	3,4-methylenedioxymethamphetamine	500 ng/ml
OXY	Oxycodone	100 ng/ml
BUP	Buprenorphine	10 ng/ml
PPX	Propoxyphene	300 ng/ml

These tests provide visual qualitative results and are intended for in vitro diagnostic use only. It is for prescription point-of-care use only and not intended for over-the-counter sale to non-professionals.

These tests provide only a preliminary test result. For a quantitative result or to confirm preliminary positive results obtained by the QuickTox® Drug Screen Dipcard, Fastect® II Drug Screen Dipstick or Fastect® II PPX Drug Screen Dipstick tests, a more specific alternative method such as Gas Chromatography/Mass Spectrometry (GC/MS) must be used. Clinical consideration and professional judgment should be applied to any drug of abuse test results, particularly when a preliminary positive result is indicated.

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Predicate Device Comparison

Similarities		
Feature	**Subject Devices** (Fastect® II PPX Drug Screen Dipstick, Fastect® II Drug Screen Dipstick, and QuickTox® Drug Screen Dipcard)	**Predicate Device** (ACON® multi-CLIN™ Drug Screen Test Device K041685)
Intended Use	Screening Device	Screening Device
Matrix	Human Urine	Human Urine
Test Principle	Competitive immunoassay	Competitive immunoassay
Analytes	Propoxyphene	Propoxyphene
Cut-Off	300ng/ml	300ng/ml
Housing	Plastic strip holder and sleeve	Plastic strip holder and sleeve
Sample Volume	10 ml	10 ml
Target User Population	For professional, in-vitro diagnostic use	For professional, in-vitro diagnostic use
Shelf Life	24 Months	24 Months
Testing Method	Lateral Flow Immunoassay	Lateral Flow Immunoassay
Antibody/Antigen	Mouse monoclonal antibody PPX Ag	Mouse monoclonal antibody PPX Ag

Differences		
Feature	**Subject Devices** (Fastect® II PPX Drug Screen Dipstick, Fastect® II Drug Screen Dipstick, and QuickTox® Drug Screen Dipcard)	**Predicate Device** (ACON® multi-CLIN™ Drug Screen Test Device K041685)
Used in Professional or Point-of-Care Setting	Used in point-of-care settings	Used in laboratory settings
Test Strip	Single Drug/Multi-Drug	Multi-Drug
Product Design	Dip method	Dip method and drop method
Storage	Sealed pouch at 15-30°C	Sealed pouch at 2-30°C
Reading Time	5-30 min	5-8 hrs
Internal Procedural Controls	Negative control line	Positive and negative control lines

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Performance Specifications

The performance characteristics of the Fastect® II PPX Drug Screen Dipstick, Fastect® II Drug Screen Dipstick, and QuickTox® Drug Screen Dipcard devices were based on evaluations by the following analytical performance studies:

- Stability
- Optimal Read Time
- Precision
- Method Comparison
- Specificity and Interference
- Effect of pH and Specific Gravity

Conclusion

The performance characteristics studies performed demonstrate substantial equivalency between the Fastect® II PPX Drug Screen Dipstick, Fastect® II Drug Screen Dipstick, QuickTox® Drug Screen Dipcard and the predicate kit ACON™ Drug Screen test device with the same cutoff concentration of 300 ng/ml. We have demonstrated that the Fastect® II PPX Drug Screen Dipstick, Fastect® II Drug Screen Dipstick, and QuickTox® Drug Screen Dipcard are safe and effective for the qualitative detection of Propoxyphene at a cutoff concentration of 300ng/ml.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 30, 2013

Branan Medical Corporation
c/o Ms. Olivia Chan
140 Technology Dr., Suite 400
Irvine, CA 92618

Re: k122752
Trade/Device Name: Fastect® II PPX Drug Screen Dipstick
Fastect® II Drug Screen Dipstick
QuickTox® Drug Screen Dipcard
Regulation Number: 21 CFR 862.3700
Regulation Name: Propoxyphene test system
Regulatory Class: II
Product Code: JXN
Dated: January 02, 2013
Received: January 03, 2013

Dear Ms. Chan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k122752

Device Name:
Fastect® II PPX Drug Screen Dipstick Test
Fastect® II Drug Screen Dipstick Test
QuickTox® Drug Screen Dipcard

Indications for Use:

The Fastect® II PPX Drug Screen Dipstick Test is a lateral flow immunoassay for the rapid detection of propoxyphene in human urine at or above 300 ng/mL.

The Fastect® II Drug Screen Dipstick and QuickTox® Drug Screen Dipcard are lateral flow immunoassay for the rapid detection of multiple drugs and drug metabolites in human urine at or above the following cutoff concentration:

THC	11-nor-Δ9-Tetrahydrocannabinol-9-carboxylic acid	50 ng/ml
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AMP	Amphetamine	1000 ng/ml
PCP	Phencyclidine	25 ng/ml
BZO	Oxazepam	300 ng/ml
BAR	Secobarbital	300 ng/ml
MTD	Methadone	300 ng/ml
TCA	Nortriptyline	1000 ng/ml
MDMA	3,4-methylenedioxymethamphetamine	500 ng/ml
OXY	Oxycodone	100 ng/ml
BUP	Buprenorphine	10 ng/ml
PPX	Propoxyphene	300 ng/ml

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S
2013.01.29 06:58:43 -05'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health
510(k) k122752

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These tests provide only a preliminary test result. For a quantitative result or to confirm preliminary positive results obtained by the QuickTox® Drug Screen Dipcard, Fastect® II Drug Screen Dipstick or Fastect® II PPX Drug Screen Dipstick tests, a more specific alternative method such as Gas Chromatography/Mass Spectrometry (GC/MS) must be used. Clinical Consideration and professional judgment should be applied to any drug of abuse test results, particularly when a preliminary positive result is indicated.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

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Denise Johnson-lyles -S
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